



# Handling the Misalignment of Interests in Assisted Reproductive Technology Practices

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# **Handling the Misalignment of Interests in Assisted Reproductive Technology Practices**

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**Class of 2011**

**May 2010**

**This paper is submitted in satisfaction of the course requirement.**

## **Abstract**

One of the major problems we see in the use of reproductive technology at this time is that there is very little regulation of embryo transfer practices that lead to multigestational pregnancies. While the FDA must approve assisted reproductive technology (ART) devices and

drugs that stimulate ovulation, it has no jurisdiction over the practice of medicine, how these drugs and devices are used on the ground, often in off-label procedures. The only current regulation of these practices is at the state level in the form of tort suits and actions against practitioners' licenses by medical boards and informally through professional society guidelines.

Tort suits are uncommon because reproductive technology is generally used by vulnerable couples, who consent to the practices that cause multiple gestation pregnancies. What suits have been brought are rarely reported and generally settle. Where couples fail to bring suit, the state guardian ad litem could intervene to bring a wrongful life suit on behalf of the resulting children, but these claims have little traction because a preterm baby may have medical problems but often does not have a life not worth living. The dangers to mothers also go unrecognized because of their consent to the procedure. State medical boards generally only act when they receive complaints, unlikely based on the alignment of interests of the target population, and, while professional societies have made strides in improving embryo transfer guidelines, they have little beyond symbolic means of enforcing their best practices.

The U.S. has a history of leaving health professionals a wide degree of autonomy to practice medicine. While it may be difficult to interfere in the relationship of individuals or couples and their relationship to their doctor, there is a strong population level dictate to intervene. This could be accomplished through federal legislation or by state action. Many sick babies are brought into the world through increased use of assisted reproductive technology and the lives of mothers are put at risk. We need to find a way to line up incentives to stop or significantly reduce the number of multiple infant births.

## **I. Introduction**

There are many controversial issues surrounding the use of reproductive technology. From parents' rights, surrogacy, gender politics and heteronormative laws, down to concerns about embryos, abortion, the beginning of life, and the safety of the technology, there is a lively scholarly debate taking place. This paper will focus primarily on the seeming gap in the regulation of how reproductive technology is used and the problem of multiple birth pregnancies.

While the Food and Drug Administration provides review and approval of medical devices and drugs for specified uses, it has no jurisdiction over the practice of medicine – how approved drugs and devices are used by physicians. Off-label use of drugs and devices, however, has been an area of concern for many. The primary way in which these uses are regulated is through tort suits at the state level and through actions against health professionals' licenses by state medical boards.

The alignment of interests at the state level, however, means that these forms of recourse have limited effectiveness within the context of reproductive technology. While individuals often must make medical decisions under great stress in a treatment environment, women undergoing fertility treatment with artificial reproductive technology are asked to consent to risks far beyond those of a normal pregnancy and to make decisions regarding potential future beings. These women may be unable to make adequately informed consent to the procedures that result in multiple births both for themselves and for their potential offspring. Compounding the consent bias is the fact that once women or couples give birth to multiple infants with all the attendant health problems, they are less likely than other types of patients to file a complaint against the physician who induced the pregnancy or to bring suit. These new parents may avoid litigation because they feel responsible or because they are happy to simply have children, regardless of their health status.

The state may intervene on behalf of the child, instating a guardian ad litem to bring a wrongful life suit, but most states refuse to recognize this cause of action and, while the medical harms to preterm and multigestational children are significant and troubling, they often do not rise to the strict requirements necessary to meet a wrongful life claim.

Over time, professional societies in the United States have updated their best practice guidelines for reproductive technology to reduce the number of embryos implanted through IVF. This has had the effect of lowering the percentage of triplets and higher-order births. However, the absolute number of these births has tended to remain constant as a larger number of women avail themselves of the use of reproductive technology. Further, the reduction in multiple birth pregnancies as a result of IVF has been counteracted to some extent by the increased use of cheaper, less invasive drugs that stimulate ovulation and do not provide an opportunity for practitioners to limit the number of embryos formed in utero. Additionally, professional societies cannot regulate effectively, despite their expertise, due to limited enforcement power. At the most, they can take away membership from members of their organizations.

The significant, negative effects of multiple births on women, offspring, and society as a whole militate for some form of regulation. Though there is no clear course for regulating these technologies through existing mechanisms, a federal law providing the FDA jurisdiction to enforce professional society guidelines or to make its own best practices may be a proper remedy. Alternately, the FDA could act to withdraw ARTs based on post-market surveillance. Because the enormous costs of multiple birth events and subsequent health care are often ultimately borne by state insurance, medical enterprises, and social services, a suit by the state attorneys general against practitioners and reproductive technology clinics may be a more direct and efficient way of exerting pressure than federal action to reduce the number of multiple births.

## **II. Consent**

Consent is a crucial aspect of the use of reproductive technologies because it helps create the space for higher risk multifetal pregnancies. As doctors exercise their discretion to use ARTs off label, they work with a patient to make that decision in light of the degree of risk or probability for success the patient is willing to trade off.

There are several unique aspects of reproductive technology that complicate informed consent. For one, the mother is consenting not just to the risks entailed in the natural course of pregnancy, but to the higher risks involved in assisted reproduction, particularly the heightened probability of higher-order pregnancy. Further, couples using reproductive technology have often been trying for a very long time to have children, meaning that decisions about which procedures to use are made under the stress of an intense desire for children, relationship pressures built up around infertility problems, financial strain from extended treatment, and concerns about the health of the mother and resulting children. While many medical decisions are made under stress, the difference in this case is that consenting to a fertility procedure is not just a mother consenting to a risk for herself or a next of kin consenting to risk for an existing person based on known or imputed desires, it is a mother and/or father consenting to risks for currently nonexistent potential beings.

The risks ARTs generate for as yet nonexistent beings create difficulties. It is impossible to use substituted judgment for a person who has not yet had the opportunity to exercise any judgment. Nor is it possible to exercise best interests properly because the best interest of any nonexistent individual is to be born, barring any catastrophically painful and extremely curtailed existence. This means that at first glance, it may be unclear that two healthy children are preferable to four sick children. However, adding to the calculus the dramatically increased risk to the mother, an already existing being, of a higher-order multifetal pregnancy the formula would seem to militate in favor of a

singleton or twin pregnancy over the good of bringing additional infants into existence at increasing risk to their health and the mother's.

From a societal point of view, it is also possible to rationally prefer bringing one or two healthy babies into existence rather than three or four chronically ill infants. As a society, we may prefer to pay for the care of the potentially healthy twin or singleton rather than the greater risk and higher cost of triplets or quadruplets.

The divergence between societal interests and the personal interest of women and couples is that the latter parties, having spent months, possibly years, and untold amounts of money and emotional capital, may not be willing to risk yet another unsuccessful fertility cycle for a safer, healthier, singleton pregnancy. Implanting fewer embryos to preclude a higher order pregnancy means that couples run a higher risk that no embryos will implant in that particular cycle. For couples that have limited insurance coverage or funds and therefore, limited ability to pay for additional fertility cycles, one or two rounds may be all the opportunity they have to create a pregnancy. These couples may be more willing to implant a greater number of embryos to ensure a greater probability of success, trading off the health of the potential offspring. While society may trade off costs and health against number of people in a community, a couple is trading off multiple potentially unhealthy children against the possibility of no children at all.

Society must weigh the degree to which it is willing to support couples and individuals who would choose to have multiple unhealthy children rather than no children at all. This becomes increasingly important in light of the fact that much of the costs of higher-order multifetal pregnancies, deliveries, and lifelong social services will be paid by society. While society may reasonably allow individuals and couples to create risks for themselves as existing persons who can bear some or all of the cost of their decisions, society has greater latitude to intervene where it will foot the bill by allowing women to take on risks of pregnancy far greater than those inherent in natural pregnancies and where that decision places lives and quality of life for as yet nonexistent beings at stake.

### **III. The Harms**

The way in which in vitro fertilization (IVF) and other assisted reproductive technology (ART) is currently practiced has given rise to a number of dangerous and expensive risks to both mothers and infants. IVF and similar techniques are responsible for dramatic increases in the number of multifetal births in the United States, which in turn raises the incidence of preterm delivery and low birthweight. Families move forward with multifetal pregnancies despite a commonly recognized correlation between multifetal births and low birthweight, as well as preterm delivery, for a number of reasons. Parents may not fully understand the attendant risks and consequences of preterm delivery.<sup>1</sup> Alternately, infertile parents may be overly optimistic in their assessment of risks or they may knowingly take on the greater risk of multifetal pregnancy because they cannot afford, or their insurance will not cover, additional treatment cycles.<sup>2</sup> For whatever reasons ART-induced multifetal pregnancies are carried forward, they present a serious and avoidable harm to society.

#### **a. Increased Incidence of Higher-Order Births in ART**

According to CDC statistics tracking assisted reproductive technology, ART causes a disproportionate number of twins, triplets, and higher-order births. In 2003, ART accounted for 1.1% of total infants born in the United States, but 44.2% of triplets and 16.4% of twins.<sup>3</sup> In 2006, ART was responsible for 1.2% of births but resulted in 37.9% of triplets and 17% of twins.<sup>4</sup> Although there was a decrease in the reported number of infants born in triplet or higher-order births over the intervening three years (3,390 to 2,477 in 2006), the reported number of twins born to parents using ART

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<sup>1</sup> David Adamson, M.D. & Valerie Baker, M.D., *Multiple Births From Assisted Reproductive Technologies: A Challenge That Must be Met*, 81 FERTILITY AND STERILITY, 517, 518 (2004) (Noting that “only 35% of the public appreciates that prematurity is a common and serious public health problem”).

<sup>2</sup> *Id.* at 518.

<sup>3</sup> Victoria Clay Wright et al., *Assisted Reproductive Technology Surveillance – United States, 2003*, MMWR CDC (2006).

<sup>4</sup> Saswati Sunderam et al., *Assisted Reproductive Technology Surveillance – United States, 2006*, MMWR CDC (2009).



increased dramatically, from 21,057 in 2003 to 23,284 in 2006.<sup>5</sup> It should be recognized that the incidence of births is underreported in these surveillance data and that higher-order multifetal pregnancies may be underreported.

A study by independent researchers corroborated CDC reports by finding that professional society-recommended limits on the number of embryos transferred in IVF did result in a significant drop in the percentage of higher-order multiple births to total ART births.<sup>6</sup> However, it also concluded that a 67% increase in total ART births and an increase in the number of triplets produced through ovulation induction held the actual number of higher-order multiple births constant.<sup>7</sup>

With regard to maternal age, ART contributions to twin and triplet births are shown to increase significantly with the age of the mother, a correlation that directly relates to absolute pregnancy risks as well.<sup>8</sup> This means that mothers who are most at risk for complications even in a singleton pregnancy are more likely than lower risk mothers to have twins, triplets, or higher-order pregnancies.

#### **b. Harms of Higher-Order Pregnancy and Deliveries to Mothers**

The risks to mothers in multifetal pregnancies and births are myriad. Mothers of twins, triplets, or higher-order births are at a 2- to 3-fold greater risk of maternal mortality.<sup>9</sup> The odds ratio of postpartum bleeding is 4.0 in multigestational pregnancies as compared to mothers of singletons, and hypertension occurs at 2 to 3 times the regular

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<sup>5</sup> *Id.* at ; Wright, *supra* note 3.

<sup>6</sup> Richard P. Dickey, *The Relative Contribution of Assisted Reproductive Technologies and Ovulation Induction to Multiple Births in the United States 5 Years After the Society for Assisted Reproductive Technology/American Society for Reproductive Medicine Recommendation to Limit the Number of Embryos Transferred*, 88 *Fertility and Sterility*, 1554, 1557, 1559 (2007).

<sup>7</sup> *Id.* at 1557, 1559. The author goes on to note that the number of triplet or higher-order births dropped from 12.5% to 6.4% of IVF pregnancies, but over that same time period (1998 to 2003) twin births conceived by ART increased 65%, accounting for 45% of the total increase in twin births. *Id.* at 1557.

<sup>8</sup> Meredith A. Reynolds et al., *Trends in Multiple Births Conceived Using Assisted Reproductive Technology, United States, 1997-2000*, 111 *Pediatrics*, 1159, 1161-62 (2003) (ART accounts for 65.4% of twins and 92.8% of triplets or higher-order births for women 45-49 years of age).

<sup>9</sup> Adamson & Baker, *supra* note 1, at 517.

rate.<sup>10</sup> Further, mothers with multifetal pregnancies have higher rates of polyhydramnios (excess of amniotic fluid in amniotic sac, associated with a number of birth defects), premature labor with prolonged bed rest, and cesarean section.<sup>11</sup> There is an odds ratio of 1.6 for gestational diabetes in mothers of multifetal pregnancies and 1.5 for maternal anemia.<sup>12</sup> Antepartum bleeding from abnormal placentation occurs twice as often and multifetal pregnancies are generally associated with more nausea and vomiting, fatigue, weight gain, and lack of sleep.<sup>13</sup> The physical nature of these extensive health issues complicates pregnancy far beyond that experienced by mothers of singleton infants and incapacitates women to a much greater degree both before birth and after.

Maternal complications go beyond physical health factors to the emotional and psychological. Mothers tend to experience exhaustion, major depressive illness, and psychological problems following multiple births.<sup>14</sup> They are at increased risk for impaired maternal bonding as well.<sup>15</sup> These health problems contribute to marital disharmony, may aggravate an already problematic lack of help in the home, and can make it difficult to mitigate sibling differences.<sup>16</sup> The implications of maternal mental and physical health problems bear serious consequences for the fetuses and infants as well as for the family as a whole.

### **c. Harms to Infants in Higher-Order Pregnancy and From ART**

Beyond health concerns for mothers carrying multifetal pregnancies are the harms that can occur to unconsenting fetuses carried in multiple gestation pregnancies. Even in singleton births from ART, infants are at 2.6 times greater risk of low birth weight.<sup>17</sup> Accounting for the increased percentage of multiple births caused by ART, findings show

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<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* at 518.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> Laura A. Schieve et al., *Low and Very Low Birth Weight in Infants Conceived With Use of Assisted Reproductive Technology*, 346 N ENG J MED 731, 734 (2002).

that ART conceived infants are at even more dramatically disproportionate risk for low birth weight and very low birth weight – ART-conceived infants comprised 0.6% of babies born in the study target population, but made up 3.5% of the low birth weight infants and 4.3% of the very low birth weight population.<sup>18</sup>

Similar findings were borne out in CDC surveillance of ART-conceived infants. In 2003, of reported infants, 32.4% of triplets or higher-order births had very low birth weight and 93.7% had low birth weight.<sup>19</sup> These statistics were actually slightly worse in 2006, when very low birth weight reports for triplets or higher-order births increased to 34.3% and 95.8% were reported with low birth weight.<sup>20</sup> Ninety-seven percent of these deliveries were preterm.<sup>21</sup> Reports to the CDC for twins showed more promising but still problematic birth weight rates for twins conceived through ART over triplets. In 2003, 56% of twins suffered low birth weight and 8.4% very low birth weight.<sup>22</sup> The reported rates in 2006 are substantially similar.<sup>23</sup> Sixty-five percent of ART-conceived twins were born preterm in those reporting years.<sup>24</sup> The CDC reports confirm the above study's finding that even singletons produced through ART tend to display an increased incidence of low birth weight (9.3%) and very low birth weight (1.9%) relative to the general population (6.49% low birth weight and 1.14% very low birth weight).<sup>25</sup> However, while still troubling, the rate in ART singletons of low birth weight and very low birth weight is considerably better than that of either twins or higher-order pregnancies. The rate of premature birth is also vastly improved as ART-conceived

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<sup>18</sup> *Id.* at 734.

<sup>19</sup> Wright, *supra* note 3.

<sup>20</sup> Sunderam, *supra* note 4.

<sup>21</sup> *Id.*

<sup>22</sup> Wright, *supra* note 3.

<sup>23</sup> Sunderam, *supra* note 4.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*; Wright, *supra* note 3; Joyce A Martin, et al., *Births: Final Data for 2006*, NAT'L VITAL STAT. REP., Jan. 7, 2009 at 19.

singletons were reported at 14.3% born preterm in comparison to 65% for twins and 97% for triplets and higher-order births in 2006.<sup>26</sup>

Aside from increased incidence of low and very low birth weight, multifetal pregnancies carry a number of other risks. Twins are five to ten times more likely than singletons to die in the period just before or after birth.<sup>27</sup> They are also at higher risk of mortality in childhood.<sup>28</sup> Triplet mortality in the first month of life is over 20 times that of singleton infants.<sup>29</sup> Other morbidities for which they face increased risks are congenital anomalies, cerebral palsy (at a 4- to 5-fold higher rate), intracranial hemorrhage, and blindness.<sup>30</sup> A greater incidence of respiratory distress, patent ductus arteriosus (defect in which the aorta and pulmonary artery remain connected after birth), and sepsis also plagues infants conceived by ART.<sup>31</sup> One expert noted that for many women “twin birth is an undesirable outcome of ART” and “single embryo transfer (SET) provides the best chance for a healthy infant.”<sup>32</sup> It goes without saying that triplet and higher-order multiple birth pregnancies present even more unacceptable risks.

#### **d. Higher-Order Pregnancy Harms Cause Increased Medical Costs**

Increased health risks to mother and child translate into increased medical costs for families, insurance, and taxpayers as a whole. In 2000, the cost of ART-conceived multifetal deliveries was projected at \$39,000 to \$58,865 for twins.<sup>33</sup> For triplets and quadruplets it ranged from \$281,698 up to \$340,000.<sup>34</sup> Since then, the actual cost of delivery has been quoted at an average of \$9,845 for singletons, \$37,947 for twins, and

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<sup>26</sup> Sunderam, *supra* note 4.

<sup>27</sup> Adamson & Baker, *supra* note 1, at 517.

<sup>28</sup> *Id.* at 517.

<sup>29</sup> *Id.* at 518.

<sup>30</sup> *Id.*; Dickey, *supra* note 6, at 1559.

<sup>31</sup> Adamson & Baker, *supra* note 1, at 517.

<sup>32</sup> Dickey, *supra* note 6 at 1559.

<sup>33</sup> Meredith Reynolds et al., *Does Insurance Coverage Decrease the Risk for Multiple Births Associated with Assisted Reproductive Technology?*, 80 Fertility and Sterility 16, 17 (2003).

<sup>34</sup> *Id.* at 17.

\$109,765 for triplets.<sup>35</sup> This added up to \$640,000,000 in additional hospital expenses related solely to ART-conceived multiple gestation pregnancies in the year 2000 alone.<sup>36</sup> Increased incidence of low birth weight and very low birth weight in multifetal ART pregnancies is an especially critical contributor, based on the fact that very low birth weight infants can cost “24-fold to 44-fold more during the first year of life than do normal-birth-weight infants.”<sup>37</sup>

The additional costs of multifetal pregnancies are not borne by the family alone. One study found that costs for the first year of life of low birth weight multigestational infants exceeded \$1 billion and that 35% of those costs were paid by Medicare and Medicaid.<sup>38</sup> Another survey, conducted by the March of Dimes, estimated that preterm delivery cost the United States more than \$26.2 billion in 2005.<sup>39</sup> These costs are paid by everyone who pays into the healthcare system, including by federal and state Medicaid programs and taxpayers in the form of state-run hospital and health care service providers.<sup>40</sup>

To provide an example using the recent and widely publicized multifetal pregnancy of Nadya Suleman, or Octomom as the media knows her: On January 26, 2009, Ms. Suleman gave birth to octuplets who were by most accounts relatively healthy. However, the expense of caring for these “healthy” babies has already put a strain on taxpayers’ dollars. Before the birth of the octuplets, Ms. Suleman was on food stamps and federal supplemental security income and three of her six children were receiving federal disability assistance.<sup>41</sup> With no job, no money, and six children already, Ms. Suleman gave birth to octuplets who created over \$150,000 in medical costs in less than

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<sup>35</sup> Adamson & Baker, *supra* note 1, at 518.

<sup>36</sup> *Id.* at 518.

<sup>37</sup> *Id.* at 518.

<sup>38</sup> Antoinette Martin, *Multiple Births: A Wake-Up Call*, N.Y. TIMES, Feb. 8, 1996, at C1.

<sup>39</sup> March of Dimes, *The Economic Costs*, [http://www.marchofdimes.com/prematurity/21198\\_10734.asp](http://www.marchofdimes.com/prematurity/21198_10734.asp)

<sup>40</sup> *Id.*

<sup>41</sup> *Octuplets’ Mom on Welfare, Spokesman Confirms*, FOW NEWS, available at <http://www.foxnews.com/story/0,2933,490269,00.html>.

two weeks after their birth.<sup>42</sup> Figures are not available for the complete two and a half month hospital stay that was necessary to ensure her children were healthy enough to go home. Ms. Suleman has signed a deal for a UK reality TV show featuring her 14 children that guarantees \$250,000 over three years, but it is as yet unclear and still unlikely that this deal will remove her children's expenses from the use of public dollars.<sup>43</sup> Eventually, the media will lose interest in this controversial story and it may prove difficult to care for the children without that source of income.

Taking the broader social effects of preterm and low birth weight deliveries into account, the societal costs are "astronomical;"<sup>44</sup> including the treatment of lifelong disabilities and lost work for parents, one estimate places the annual total at \$50 billion.<sup>45</sup> While ART-induced multifetal pregnancies are not the sole basis for these expenditures, the disproportionate number of twins, triplets and higher-order ART births are a substantial portion of the cause. As the use of ART increases, measures must be taken to reduce the number of multifetal pregnancies and to ensure that reproductive technology does not create even more burdensome financial strains on the public.

#### **IV. Current Regulation**

In order to regulate the creation of multifetal pregnancies through use of artificial reproductive technology, physician practices in infertility treatment must be regulated. This would require imposing on the practice of medicine by limiting the number of embryos that can be transferred at a time. Both doctors and the government tend to be

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<sup>42</sup> *Report: Octuplets Likely to Cost Taxpayers Millions*, Washington Times, available at <http://www.washingtontimes.com/weblogs/out-context/2009/Feb/11/report-octuplets-likely-to-cost-taxpayers-millions/>.

<sup>43</sup> *Nadya Suleman and Octuplets to Star in Reality TV Show*, The Times of London (July 26, 2009) at [http://www.timesonline.co.uk/tol/news/world/us\\_and\\_americas/article6727995.ece](http://www.timesonline.co.uk/tol/news/world/us_and_americas/article6727995.ece).

Even so, Ms. Suleman is dealing with foreclosure on her house.

<sup>44</sup> Catherine A Clements, *What About the Children? A Call for Regulation of Assisted Reproductive Technology*, 84 Ind. L.J. 331, 344 (2009) (citing Spencer E. Ante, *Million-Dollar Babies*, BUSINESS WEEK, June 23, 2008, at 46.)

<sup>45</sup> *Id.*

uncomfortable with interference in the patient-physician relationship, which has led to fairly weak regulation of the practice of medicine.

#### **a. Federal Regulation**

Once the Food and Drug Administration (FDA) has approved a drug or device as safe and effective for a specific use, including a label with appropriate directions and warnings, a physician may generally use that drug or device as he or she deems fit. Off-label use is extremely common and only minimally limited by tort suits and complaints to state medical boards against a physician's license. Several federal laws add additional restraints, but they are based around surveillance and purity standards. Further, they lack effective enforcement mechanisms.

The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) is a federal law that creates a reporting system to provide feedback and enhance physician practice of fertility treatment as well as enable consumers to make informed decisions.<sup>46</sup> The FCSRCA requires annual reporting of clinic specific success rates that are then published by the CDC along with a list of clinics that failed to report.<sup>47</sup> The law also called for development of a model program for certification of embryo laboratories and promulgation of criteria and procedures for approval of accreditation programs to inspect and certify embryology laboratories.<sup>48</sup>

Despite the utility of the reporting that the FCSRCA requires, there are several gaps in the way the law has functioned in practice. Although, 90% to 95% of clinics report on an annual basis, the law apparently lacks sufficiently heavy financial penalties

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<sup>46</sup> David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 39 FAM. L.Q. 727, 731 (2005); THE FERTILITY CLINIC SUCCESS RATE AND CERTIFICATION ACT OF 1992, PUB. L. NO. 102-493, *codified* at 42 U.S.C.A. §§ 201, 263(a)(1-7) (Supp. 1994).

<sup>47</sup> Adamson, *supra* note 43, at 731.

<sup>48</sup> *Id.*

to ensure compliance of the last 5% to 10%.<sup>49</sup> Also unsuccessful in enforcing compliance is the public shame of adding nonreporting clinics to a list on the CDC website.<sup>50</sup>

The larger problem is that the CDC is not an enforcement agency, but a surveillance agency. The fact that this law is based within the CDC attests to its primarily descriptive rather than regulatory goals. In fact, one theory goes so far as to assert that the surveillance function has had a perverse effect with regard to regulation. Rather than deterring multifetal pregnancies, publication of clinic-specific success rates is thought to have lead infertile couples to compare fertility clinics in a way that has increased the number of multigestational pregnancies.<sup>51</sup> As clinics compete to improve success rates they implant embryos beyond the recommended amount for a given woman's prognosis, causing unnecessary multiple pregnancies, in order to raise the probability that at least one embryo develops to viability. Evidence shows that the percentage of higher-order multiple pregnancies has declined in recent years, hopefully indicating a retreat from the competition engendered by the FCSRCA, but the general rate of multifetal pregnancies is likely much higher than it might otherwise have been.<sup>52</sup>

The final major issue with the FCSRCA, which affects much of federal health care regulation, is that the model program for embryo laboratory certification has to be implemented by individual states and most states have not adopted it.<sup>53</sup> Because most medicine and healthcare issues are regulated under state police powers, the states have the ultimate authority in deciding whether to implement a certification program.

Other federal guidelines are focused on establishing the origin of tissues and their purity through donor screening and good tissue practices. These regulations were written by the FDA and include the following: The Establishment Registration and Listing for

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<sup>49</sup> *Id.*; JUDITH DAAR, REPRODUCTIVE TECHNOLOGIES AND THE LAW 688 (Matthew Bender & Co. 2006).

<sup>50</sup> Adamson, *supra* note 43, at 731.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*; Wright, *supra* note 3; Sunderam, *supra* note 4.

<sup>53</sup> Adamson, *supra* note 43, at 732.



Human Cells, Tissues and Cellular-based Products, effective January 21, 2004,<sup>54</sup> the Eligibility Determination for Donors of Human Cells, Tissue and Tissue-based Products, effective May 25, 2005,<sup>55</sup> and the Current Good Tissue Practice for Human Cell, Tissue and Cellular and Tissue-based Product Establishments: Inspection and Enforcement, effective May 25, 2005 but only encouraged for reproductive tissues.<sup>56</sup> While the FDA enforces these regulations with unannounced onsite inspections and heavy fines<sup>57</sup>, these regulations fail to address the central issue of practices that result in multifetal pregnancies. They address the materials involved rather than the transfer of embryos.

The FDA took stronger measures with regard to one form of ART. It announced in 2001 that it considered ooplasm transfer (practice in which cytoplasm from a donor egg is injected into a woman's egg to increase probability of fertilization and implantation in older eggs) a clinical investigation.<sup>58</sup> This meant that any clinic practicing the procedure would have to submit a New Drug application, a drawn out process that ultimately precluded the practice altogether in the U.S.<sup>59</sup> Some authors presume the FDA took this stance because ooplasm transfer had the effect of creating infants with three genetic parents.<sup>60</sup> While it may have been justified in stamping out this particular technique, such a crude approach to IVF, GIFT, ZIFT, or other common forms of ART may not be so easily executed or excused. ART provides an invaluable service, and the goal in regulating ART is to ensure that it is practiced safely, not to stop the practice altogether.

#### **b. Professional Society Guidelines**

Guidelines for best practices in treatment of infertility were set out by the American Society of Reproductive Medicine (ASRM), a professional society that has

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<sup>56</sup> Adamson, *supra* note 43, at 736.

<sup>57</sup> *Id.*

<sup>58</sup> DAAR, *supra* note 49, at 690; Adamson, *supra* note 43, at 735-36.

<sup>59</sup> DAAR, *supra* note 49, at 690.

<sup>60</sup> *Id.*, at 690.

only symbolic enforcement methods. As a professional society, ASRM does not in fact regulate the practice of medicine. It does not have the authority to take away the medical license of individuals who stray too far from the guidelines and the fact that the guidelines ASRM promulgates are created by practitioners to regulate their own field opens its dictates up to a host of criticisms involving protectionism and self-interest. Still, ASRM, being a professional society is in the best position to provide expert evaluations regarding the state of technology and best practices. Moreover, it is in fertility practitioners' best interests to regulate their field to the extent that it improves their standing in the public eye. Whether this positive image is illusory is a question for another paper, but to the extent that multifetal pregnancies are discouraged, ASRM and other reproductive technology societies have "actively advocated" for federal regulation of embryo transfer practices.<sup>61</sup>

In the absence of direct federal or state regulation, ASRM and the Society for Assisted Reproductive Technology (SART) promulgated best practices to guide their members. The guidelines are based on collaborative work performed by the ASRM Practice Committee and Ethics Committee. The Ethics Committee, composed of six doctors/practitioners, four lawyers, four bioethicists, and an individual with a law degree and a medical degree,<sup>62</sup> recommended that fertility clinics should strive to eliminate quadruplet pregnancy and reduce the rate of triplets to 1-2% of all pregnancies.<sup>63</sup> With these goals in mind, the Practice Committee set out guidelines in 1998 that it updated in 1999 to the following: (1) women under age 35 with a good to adequate prognosis should receive 2 good quality embryos, (2) women under 35 with a worse prognosis should have

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<sup>61</sup> Adamson, *supra* note 43, at 734.

<sup>62</sup> Because the Ethics Committee is not listed anywhere or on the ASRM website, or is only listed on the Ethics Committee site, which is not available to nonpaying members of the Society, this list was taken from a recent publication by the committee. The exact composition is five MDs, an MD PhD in physiology, four PhDs in bioethics, psychology, and counseling, four JDs, an individual with an MD, PhD, and JD, and an individual with an MA. The Ethics Committee of the American Society for Reproductive Medicine, *Access to Infertility Treatment by Gays, Lesbians, and Unmarried Persons*, 92 Fertility and Sterility 1190, 1192 (2009).

<sup>63</sup> Adamson & Baker, *supra* note 1, at 518

3 embryos implanted, (3) four embryos should be transferred for women between 35 and 40, and (4) women over 40 should receive five good quality embryos.<sup>64</sup>

Since then, the guidelines have been updated to reflect a more cautious approach. No more than two embryos should be transferred to anyone under 35, regardless of prognosis, with advice to consider a single embryo transfer.<sup>65</sup> Women aged 35 to 37 with a favorable prognosis should receive no more than 2 embryos, but all others may still receive 3.<sup>66</sup> Four embryos may be transferred to patients between 38 and 40 years of age, but practitioners are advised to transfer no more than three embryos for women with a favorable prognosis.<sup>67</sup> Finally, for those patients between ages 41 and 42, five embryos are recommended.<sup>68</sup> Essentially, these new guidelines separate the age group of 35-40 year old women into two classes and adjust the number of embryos transferred to women with favorable prognoses down by one for the 35 and under and the 35-37 year old age group.

Adherence to the guidelines set out by ASRM is bolstered by SART enforcement. SART requires all member physicians to make a note in the medical record of patients for whom the guidelines were not followed.<sup>69</sup> Random on-site inspections are then employed to assess compliance.<sup>70</sup> Should any ART program fail to follow proper protocols, it risks losing its SART membership.<sup>71</sup> Over 90% of IVF cycles in the U.S. are performed by SART members, meaning that theoretically, the SART/ASRM-recommended best practices should govern just as much of the practice of assisted reproductive technology.<sup>72</sup>

Based on the promulgated guidelines and enforcement mechanisms, it would seem that ART is being brought under control through self-regulation. However,

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<sup>64</sup> *Id.* at 518.

<sup>65</sup> ASRM, *Guidelines on Number of Embryos Transferred*, 92 Fertility and Sterility 1518, 1518 (2009).

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> Adamson & Baker, *supra* note 1, at 519.

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> Adamson, *supra* note 43, at 734

although professional societies provide a veneer of credibility, it is important to consider the rigor with which they evaluate their members and the way in which they balance the appearance of legitimacy against protecting members of the field. The rate of twin and triplet births is still at unacceptably high levels and the rate of twin births continues to grow. We have yet to see evidence in ART birth trends of the growing consensus outside the ART practitioner community in favor of single embryo transfer.<sup>73</sup>

### **c. State Regulation**

The major penalties that do exist for ART practitioners are applied by the states. It is through the police powers of the state that a physician's license can be suspended or revoked. When a physician fails to meet the standard of practice, that failure is recognized by action of the state medical board or by civil claims made in court against the doctor.

A number of states have passed laws that bear indirectly on embryo transfer practices in ART but few have laws that comprehensively regulate the process. Following the birth of octuplets to Nadya Suleman in January 2009,<sup>74</sup> caused by the implantation of more than six embryos,<sup>75</sup> many states introduced proposed laws to restrict the practice of IVF.<sup>76</sup> It still remains to be seen what will come of those laws. However, in California, where the Suleman octuplet pregnancy was induced and birth occurred, the presented bill was ultimately rejected. Senator Gloria Negrete McLeod introduced a bill that would make fertility clinics separate from hospitals subject to accreditation requirements.<sup>77</sup> Most clinics in California are currently run privately by physicians and

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<sup>73</sup> Dickey, *supra* note 6, at 1559.

<sup>74</sup> Nadya Suleman – Highlights, <http://www.chicagotribune.com/topic/social-issues/family/parent-child/nadya-suleman-PECLB0004513.topic>

<sup>75</sup> Pet. Compl. Med. Bd. CA, Case No. 06-2009-197098, 6 available at <http://licenselookup.mbc.ca.gov/licenselookup/lookup.php?LicenseType=G&LicenseNumber=41227>

<sup>76</sup> SUSAN L CROCKIN & HOWARD W JONES, LEGAL CONCEPTIONS: THE EVOLVING LAW AND POLICY OF ASSISTED REPRODUCTIVE TECHNOLOGIES 107 (2010).

<sup>77</sup> Greater Oversight of Fertility Clinics and Cosmetic Surgery Centers Sought, [http://dist32.casen.govoffice.com/index.asp?Type=B\\_PR&SEC=%7B78A8DE90-C93C-](http://dist32.casen.govoffice.com/index.asp?Type=B_PR&SEC=%7B78A8DE90-C93C-)

are unregulated by the Department of Public Health or any accrediting agency.<sup>78</sup>

Although the bill was passed by the senate, Governor Schwarzenegger vetoed it in October 2009, commenting that, because it failed to require a license and lacked meaningful enforcement mechanisms, it was not a strong enough measure.<sup>79</sup> No other regulatory action has been taken since.

Other states have enacted laws regarding insurance coverage, written contracts in provision of IVF services, advertising, counseling, and reporting.<sup>80</sup> Louisiana comes closest to what a model federal law might look like, requiring that ART practitioners, clinics and personnel adhere to professional society guidelines.<sup>81</sup> However, the specific standards referenced are the skill and training of the practitioner and the quality of the clinic. While these may encompass the limits of professional societies on number of embryos transferred, it is not clear that the statute must be interpreted to include every guideline issued by professional societies. It may still leave broad discretion to licensed physicians in determining the number of embryos to transfer to any given woman.

New Hampshire law focuses primarily on the health of the participants prior to undergoing an ART procedure but fails to consider the health effects of the procedure or specific methods of practicing IVF that could compromise patient health. The regulations require all women, gamete donors, and gestational surrogates to be found “medically acceptable” before they may undergo the procedure.<sup>82</sup> The New Hampshire requirement that couples using a gestational surrogate over 35 years of age must undergo

[4D5E-A988-B5FD4F2384E0%7D&DE=%7BD7A674B5-A012-4F64-93C6-07D2D381F29D%7D](#) (last visited May 12, 2010).

<sup>78</sup> *Id.*

<sup>79</sup> Schwarzenegger veto of SB674, available at: [http://leginfo.ca.gov/pub/09-10/bill/sen/sb\\_0651-0700/sb\\_674\\_vt\\_20091012.html](http://leginfo.ca.gov/pub/09-10/bill/sen/sb_0651-0700/sb_674_vt_20091012.html)

<sup>80</sup> CHARLES P. KINDREGAN, JR. & MAUREEN MCBRIEN, ASSISTED REPRODUCTIVE TECHNOLOGY: A LAWYER’S GUIDE TO EMERGING LAW AND SCIENCE 81 (2006); States requiring insurance coverage for IVF procedures include Arkansas, Hawaii, Maryland, Illinois, New Jersey, and Texas. ARK. CODE ANN. §§23-85-137, 23-76-118 (West 2004); HAW. REV. STAT. ANN. §431:10A-116.5 (2004); MD. ANN. CODE §15-810 (West 2004); ILL. COMP. STAT. ANN., ch. 215, § 5/356m (2004); N.J. STAT. ANN. § 17:48-6x (West 2004); Tex. INS. CODE ANN. tit. 1, ch. 3, § 51-6 (2004).

<sup>81</sup> La. Rev. Stat. Ann. §9:128

<sup>82</sup> N.H. Rev. Stat. Ann. §§ 168-B13, 168-B16, 168-B18, 168-B19.

genetic counseling and the inclusion of counseling for any woman or parents planning to create a child through ART with their own gametes and bodies is a nod to the dangers of the procedure.<sup>83</sup> However, these regulations still leave open the option of transferring any number of embryos. Individuals and couples seeking infertility treatment are vulnerable and may choose dangerous multifetal pregnancies even with counseling.

Pennsylvania and Virginia laws are centered upon reporting requirements. In Virginia, consent forms include the success rates and various other statistics for the particular procedure being contemplated.<sup>84</sup> However, the regulation includes no further disclosure of risks, benefits, or alternatives – part of the “traditional calculus” in receiving medical consent.<sup>85</sup> Whereas Virginia requires reporting to specific individuals about the relevant contemplated procedure, Pennsylvania’s reporting requirement is much broader, mandating public accounting of the location and personnel at each clinic as well as the number of eggs fertilized, implanted, and discarded.<sup>86</sup> Despite the utility of reporting, the same concerns addressed to the ASRM/SART reporting through the CDC apply to these regulations. They fail to address the central problem of multifetal pregnancies and may have the same perverse effect of increasing multigestational pregnancies due to patient misuse.

The general criticism of state laws reflects the central concern expressed in this paper that current regulations “generally do not impose any substantial legal restrictions on the practice of IVF,” restrictions that are necessary to reduce multifetal pregnancy.<sup>87</sup> While purity and origin are valid concerns in the practice of IVF and other types of ART, the dangers of multifetal births for mothers and infants are not being addressed quickly enough to leave this facet of ART unregulated or only indirectly regulated.

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<sup>83</sup> *Id.*

<sup>84</sup> Va. Code Ann. §54.1-2971.1

<sup>85</sup> DAAR, *supra* note 49, at 692-93.

<sup>86</sup> *Id.* at 692.

<sup>87</sup> KINDREGAN & MCBRIEN, *supra* note 80, at 81.

## V. Administrative Action

While there is some evidence that multifetal pregnancies are being addressed through tort and medical board complaints, the move to these forms of action is only recent and still rare. In really outstanding and egregious cases, it seems that factors beyond the health of the children and mother play a role in determining action against a doctor's medical license. In the octuplet case of Nadya Suleman, a complaint was filed against Michael Kamrava, M.D. on December 22, 2009, 11 months after the birth of the Suleman octuplets.<sup>88</sup> The complaint alleges gross negligence for the number of embryos transferred, stating that "the number of blastocyst embryos... should not be transferred into any woman, regardless of age," as well as complaints for gross negligence in repeatedly initiating a fresh cycle of oocyte retrieval when frozen embryos were available<sup>89</sup>, gross negligence in failing to refer patient for mental health evaluation, repeated negligent acts, and failure to keep adequate records.<sup>90</sup> Despite the serious nature of the claims made against Dr. Kamrava's license, the Medical Board of California "License Lookup System" still lists Dr. Kamrava's license as "renewed and current."<sup>91</sup> As the website notes, Dr. Kamrava is permitted to continue his practice.<sup>92</sup> Though it makes the complaint available for public viewing, the website tells the public that, as of mid-May (six months after the complaint was filed), "the physician has not had a hearing or been found guilty of any charges."<sup>93</sup> Thus, in a situation where an ART practitioner perpetrated shocking violations of the standards set forth by the ASRM, and where the

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<sup>88</sup> Pet. compl., *supra* note 72, at 1.

<sup>89</sup> Use of frozen embryos can avoid the risks of ovarian stimulation (which carries an extremely high risk of multifetal pregnancy) and oocyte retrieval.

<sup>90</sup> *Id.* at 6-11.

<sup>91</sup> Medical Board of California – Physician/Surgeon License Lookup, License Information for Michael M. Kamrava, M.D., <http://licenselookup.mbc.ca.gov/licenselookup/lookup.php?LicenseType=G&LicenseNumber=41227>.

<sup>92</sup> *Id.*

<sup>93</sup> Medical Board of California – Physician/Surgeon License Lookup, Public Record Action(s) for Michael M. Kamrava, M.D., <http://licenselookup.mbc.ca.gov/licenselookup/lookup.php?LicenseType=G&LicenseNumber=41227>

public is fully aware of the egregious nature of his acts, the Medical Board of California continues to allow this physician to practice a year and a half after his actions were made public, and even longer after he carried out the acts in question. Rather than expediting this case to send a message to other ART practitioners in the state, the Board continues to leave the grave nature of this incident unaddressed. Luckily all eight children were born healthy, which is extremely statistically uncommon, but, despite being relatively healthy, it was still two and a half months before all eight children were healthy enough to leave the hospital.<sup>94</sup>

Investigating other examples of large multifetal pregnancies produced by ART shows similar inaction on the part of state medical boards. The Chukwu octuplets, born in 1998, were the first octuplets born in the United States and were the product of fertility treatment.<sup>95</sup> One infant was born 15 weeks premature and the rest, 13 weeks premature.<sup>96</sup> The smallest child died within a week of birth from heart and lung failure.<sup>97</sup> Despite the complications and difficulties involved in the pregnancy, birth, and post-natal care, no action against Dr. Brian Kershon, the Chukwus' fertility specialist, appears on the Texas Medical Board site.

The same is true of the physician who induced the multi-fetal pregnancy that created the McCaughey septuplets, born in 1997.<sup>98</sup> Though two of the septuplets have cerebral palsy (caused by injury to the brain before, during, or after birth) and the usual difficulties surrounding pregnancy and birth of multiples were present as well, there is no

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<sup>94</sup> Bonnie Buck & Hasani Gittens, *One to Go: Octo-Mom's 7<sup>th</sup> Baby Home*, NBC, San Diego (Apr. 2, 2009) available at: <http://www.nbcsandiego.com/news/archive/Octo-Mom-Blah-Blah-Blah-7th-Baby-Home.html>; Ani Esmailian, *Octomom Brings Final Baby Home*, Hollyscoop (Apr. 14, 2009) available at: [http://www.hollyscoop.com/nadya-suleman/octomom-brings-final-baby-home\\_19899.aspx](http://www.hollyscoop.com/nadya-suleman/octomom-brings-final-baby-home_19899.aspx)

<sup>95</sup> Rick Lyman, *Mother of Octuplets Goes Home to Recover*, New York Times (Dec. 31, 1998), available at: <http://www.nytimes.com/1998/12/31/us/mother-of-the-octuplets-goes-home-to-recover.html>

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> Bobbi McCaughey, *Bobbi McCaughey's Weekly Journal*, American Baby.com, <http://web.archive.org/web/20021001222001/www.americanbaby.com/ab/CDA/featuredetail/0,1349,1323-1,00.html?s=96>.



public board action on file for Dr. Karen Drake or Dr. Paula Mahone, the McCaughey's perinatologists.<sup>99</sup> Information on Dr. Katherine Hauser, the McCaughey's fertility specialist, is not available since she retired in 2006.<sup>100</sup> However, it may be assumed, based on the phenomenon-focused media framing of the event and the massive public donations and support, that action against Dr. Hauser likely was not taken.<sup>101</sup>

## **VI. Civil Action**

Much like actions against physician licenses by state medical boards, actions taken in tort are rarely reported and generally unsuccessful. While some state common law has determined professional society guidelines to establish the standard of practice, this is not universal.<sup>102</sup> The broader problem, however, is that individuals who carry and birth multifetal pregnancies often choose to do so and therefore do not bring suit.<sup>103</sup> The rare cases where individuals have brought suit show mixed results.

In Morgan v. Christman, the U.S. District Court for the District of Kansas dismissed the defendant physician's motion for summary judgment against quadruplet plaintiffs alleging negligence, lack of informed consent, and negligent misrepresentation.<sup>104</sup> The judge ruled that the physician's assertion that the action ought to be wrongful life or wrongful birth was inappropriate because the plaintiffs were not arguing they should not have been born but that the physician's failure to inform their mother of the risks caused their premature birth and thereby birth defects.<sup>105</sup> This opinion is unpublished and the ruling on any subsequent trial, if there was one, is not published or

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<sup>99</sup> Iowa Board of Medicine, Medical License Verification, [http://medicalboard.iowa.gov/find\\_physician/index.html](http://medicalboard.iowa.gov/find_physician/index.html) (search "Karen Drake" and "Paula Mahone");

<sup>100</sup> [http://desmoines.momslikeme.com/members/JournalActions.aspx?g=246760&m=270779&source=stream\\_user](http://desmoines.momslikeme.com/members/JournalActions.aspx?g=246760&m=270779&source=stream_user) (Hauser retirement in comments).

<sup>101</sup> Michael D. Lemonick et al., *Septuplets: It's a Miracle*, Time Magazine (Dec. 1997) available at: <http://www.time.com/time/magazine/article/0,9171,987455-1,00.html>.

<sup>102</sup> KINDREGAN & MCBRIEN, *supra* note 80, at 287-88.

<sup>103</sup> *Id.*, at 275.

<sup>104</sup> 1990 WL 137405 (D. Kan).

<sup>105</sup> *Id.*

made available. As some commentators have pointed out, most of these cases settle before trial and therefore do not create binding precedent or even a record.<sup>106</sup>

Most of the literature includes only two other cases regarding embryo transfer and these are British cases that again do not create binding precedent in the U.S. What is more, they take place in a legal environment where strict limits are placed on embryo transfer practices by the Human Fertilisation & Embryology Authority (HFEA).<sup>107</sup> In the first case, a British couple sued after the birth of triplets, claiming that a prior written agreement existed in which it was agreed that only two embryos would be transferred. The couple settled with the physician for £20,000, enough to cover their legal expenses but not enough to pay for the additional child.<sup>108</sup> The second case, which did not settle, ruled in favor of the three surviving children in a set of quadruplets, awarding damages for an excessive dose of Metrodin, an ovulation induction drug, that created the multifetal pregnancy.<sup>109</sup> The quadruplets were born at 26 weeks, with severe complications – one died, one child has cerebral palsy, and a third has behavioral problems.<sup>110</sup> The fourth is healthy.

These few cases might imply that a regular negligence action or failure to warn claim may be the best route for individuals suing for multifetal pregnancy-induced harms. The difficulty, however, is verifying that couples have or are bringing these sorts of claims and determining the success of these types of claims, when hardly any reported opinions are available.

There is little in the literature regarding claims of wrongful life suits made in these situations, but, based on the general subject matter of wrongful life claims, courts have generally rejected the cause of action itself, and, where it allows the claim to

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<sup>106</sup> CROCKIN & JONES, *supra* note 76, at 30.

<sup>107</sup> Marsha Garrison, *Regulating Reproduction*, 76 Geo. Wash. L. Rev. 1623, 1624 (2008).

<sup>108</sup> CROCKIN & JONES, *supra* note 76, at 59.

<sup>109</sup> CROCKIN & JONES, *supra* note 76, at 131.

<sup>110</sup> *Id.*, at 131.

proceed, may not consider the harms to infants borne of multifetal pregnancies to rise to the level necessary to make a colorable claim.<sup>111</sup>

## **VII. Moving Forward**

Although there is evidence that the percentage of triplets and higher-order multifetal pregnancies with respect to total ART-induced pregnancies is dropping, the rates are still quite high and the rates of twin births are skyrocketing. The ASRM/SART guidelines have done a great deal to move ART practice in the right direction, but without stronger enforcement mechanisms, it may still be a number of years before embryo transfer practices at clinics are fully aligned with the professional society guidelines. Those who use the technology to have children are unlikely to insist on better adherence to transfer guidelines because problems with paying for ART treatments and the stress of extended use, despite the tradeoffs to their own and their offspring's health. States are moving slowly, constrained by standards of practice in tort and administrative actions that are not best practices and by a piecemeal approach to fertility treatment regulations. Still, there are options at the state and federal levels to improve multifetal pregnancy rates more quickly than the natural evolution in practice of medicine and self-regulation.

Although the FDA traditionally regulates drugs and devices to determine their safety and efficacy, the exception of procedures is not an obviously necessary omission at this point. The duties of the FDA have largely been determined in reaction to public catastrophes. The precursor of the administration began with legislation enacted first to counter dangers from unsafe smallpox vaccines, then more general concerns about the ability to obtain safe foods and medicine.<sup>112</sup> The Biologics Act of 1902 required drugs sold in interstate commerce to be produced in licensed establishments as a "response to the distribution in St. Louis of a tetanus-infected diphtheria anti-toxin," that killed several

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<sup>111</sup> See e.g., *Nelson v. Krusen*, 678 S.W.2d 918 (Tex. 1984); *Strohmaier v. Associates in Obstetrics & Gynecology*, 332 N.W.2d 432 (1982); *Siemieniec v. Lutheran General Hospital*, 512 N.E.2d 691 (Ill. 1987).

<sup>112</sup> PETER BARTON HUTT, RICHARD A. MERRILL, AND LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS*, 3<sup>rd</sup> Ed. 8-9 (2007).

children.<sup>113</sup> The 1906 Act, in response to Upton Sinclair's The Jungle, forbade interstate commerce in adulterated and misbranded food and drugs, creating criminal penalties and authorizing seizures for violations.<sup>114</sup> The 1938 Act provided the most basic architecture of the current FDA and brought cosmetics and devices under the purview of the Food and Drug Administration.<sup>115</sup> After 1938, major amendments included restructuring the FDA's approach to drug and device approval with the Drug Amendments of 1962 and the 1976 Medical Device Amendments, and giving it authority over pesticide limits and food and color additives.<sup>116</sup>

One reason that medical practice was not originally included was that at the inception of the FDA, and until fairly recently, it simply would not have made sense; the standard of practice for medicine was considered a local issue. Because doctors across the country had different abilities to educate and equip themselves, they could not be judged at or expected to perform at equal levels. Over time, medical education and supplies have become highly mobile. Practitioners are expected to be able to compete on a national level with their counterparts because they have access to the same informational resources. With a move to a national standard in tort, which involves evaluating the practice of medicine by similarly situated practitioners nationally, it might be conceivable to place national standards on particular procedures for regulation by the FDA.<sup>117</sup> Although medicine may be considered an artform, facets of the practice of ART can be reduced to clear technical guidelines, as indicated by the ASRM/SART guidelines. When these standards are breached, dangerous multifetal pregnancies can be caused. Standardizing ART procedures at this point to the ASRM/SART guidelines provides a reasonable certainty of safety and efficacy, fitting into the FDA's traditional mission.

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<sup>113</sup> 32 Stat. 728; HUTT, MERRILL, & GROSSMAN, *supra* note 112, at 9.

<sup>114</sup> *Id.*, at 10.

<sup>115</sup> *Id.*, at 13.

<sup>116</sup> *Id.* at 14.

<sup>117</sup> David M. Studdert, Michelle M. Mello, and Troyen A Brennan, *Medical Malpractice*, 350 N. ENG. J. MED. 283, 284 (2004).

The difficulty with adding standardized national procedures to the FDA's purview is that, such a move would create enormous administrative and enforcement issues. While the FDA would be able to provide direct criminal penalties by active inspection for failing to follow ASRM/SART guidelines or an alternate agreed upon national standard, the problem of limited resources arises. The FDA is already strapped for resources and making difficult enforcement compromises.<sup>118</sup> Unless additional funding is provided and hiring performed, the FDA may not be able to improve ART practices, or any of the other highly technical procedural medical standards that would surely be added for national enforcement because it could not carry out a sufficient number of inspections. Without more than spot enforcement, FDA penalties are unlikely to create improved national practices.

To take a less extreme measure, the FDA could take action based on post market surveillance, classifying pregnancy of triplets or higher-order, induced by ART or other fertility treatment, as an adverse event.<sup>119</sup> This type of information is already available to some extent through the CDC database. The FDA would then be able to exercise its discretion in determining whether the number of higher-order pregnancies caused by a given procedure makes it too risky to leave the drug or device on the market. The trouble with recalling certain drugs and devices however, is that ART practiced cautiously provides an incredibly valuable service to society. Only when it creates unreasonably risky pregnancies of triplets or higher may it be viewed as an unwanted threat to the public health, or unsafe and ineffective within the proper guidelines. As birth trends have shown, ART can be practiced safely; the critical issue is ensuring that it is.

Withdrawing ovarian induction drugs, however, may be an appropriate move. Though they are often cheaper and less invasive, research has shown that "62% of quadruplet pregnancies and virtually all quintuplet and higher-order pregnancies in the

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<sup>118</sup> HUTT, MERRILL, & GROSSMAN, *supra* note 112, at 19,20.

<sup>119</sup> *Id.* at 736, 1042.

United States result from ovarian stimulation alone or combined with intrauterine insemination.”<sup>120</sup>

Another possibility would be to amend the Fertility Clinic Success Rate and Certification Act to make states more likely to adopt the model laboratory and clinic certification and licensing standards. Promoting such a measure could be accomplished by tying conditional funding to it. Included in the licensing would be mandatory use of embryo transfer guidelines and license for a harsh penalty should a practitioner fail to follow those transfer practices, perhaps providing an exception for unusual medical circumstances.

A different approach, placing the initiative more directly in the hands of the states, would be to take action in the same vein as that of tobacco litigation. Just as tobacco created enormous medical expenses for states, ART-induced multifetal pregnancies have taken a toll on state Medicaid and social service funds. Although the number of multifetal pregnancies are now becoming more reasonable, at least from ART if not ovarian stimulation drugs, states have been dealing with the astronomical costs of multifetal pregnancies and the attendant health risks to their citizens through the years where multifetal rates spiked and since the assisted reproductive technology procedures were introduced. As in the tobacco litigation, the states could join together to sue the larger clinics or ART clinic insurers under the *parens patriae* powers in the interest of the health, safety, and welfare of their citizens.<sup>121</sup>

Though this would not be to recover the costs of the multifetal pregnancies, such an action would hopefully prevent future practices that induce higher-order pregnancies. It would also serve to better align state interests, placing the impetus on ART practitioners to avoid causing further multifetal pregnancies while skirting the desires of

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<sup>120</sup> Urska Velikonja, *The Costs of Multiple Gestation Pregnancies in Assisted Reproduction*, 32 Harv. J. L. Gen. 463, 468-67 (2009).

<sup>121</sup> Richard P. Ieyoub & Theodore Eisenberg, *State Attorney General Actions, the Tobacco Litigation, and the Doctrine of Parens Patriae*, 74 TUL. L. REV. 1859, 1864 (2000).

patients who want a child even at the cost of many ill children. The states could ask for an injunction to stop practices that cause multifetal pregnancies and base claims for damages on the costs to the state of past multifetal pregnancies and subsequent services. While the nature of the target presents some difficulty in bringing suit, ART services are not provided by a handful of enormous companies as are tobacco products, choosing some of the largest clinics in each state or some of the major companies that own and operate hospitals and clinics may serve the purpose.

Though large-scale litigation by state attorneys general presents some upsides, there are also complexities that could create problems. Generating legislation creates a definite standard, but bringing suit presents uncertainties if the states do not win. The states would not be able to dictate penalties and they would likely have to make compromises in the event of a settlement. The suit would likely generate a great deal of publicity and could educate the public about the potential dangers of ART, but the same conflict of interest and consent would apply to consumers whether or not they are educated about the risks. In the event that the states are successful, the suit will provide a useful precedent for individuals suing and for creating a more universal standard of care. However, the action is primarily retrospective, punishing clinics and practitioners for past acts. Efforts would have to be made to ensure an injunction or concessions about future behavior in a settlement.

Ultimately, it seems the best options would be to amend the FCSRCA to include stronger enforcement mechanisms and more enticing conditions to encourage states to adopt the model credentialing acts or to bring suit by the state attorney generals. The former provides perhaps a more solid grounding for the future, but it still encounters the problem of enforcement. Bringing suit under the *parens patriae* has the advantage being a more immediate and direct action that will avoid the misalignment of interests that has caused so many multifetal births in the past and that will compensate the states for the enormous amount of taxpayer dollars that have already gone toward ART mother and

infant expenses. Concerted action to carry forward both strategies may provide the best approach, addressing the problem both prospectively and retrospectively.

### **VIII. Conclusion**

While assisted reproductive technologies have done wonderful things for society, they have also been the cause of great and unnecessary suffering. Evidence has shown that ARTs can be used safely and successfully, but more must be done to ensure that they are in fact used properly. While the practice of medicine generally goes unregulated, but for actions at the state level, ART is an example of the rare medical procedure in which interests do not align to make these forms of recourse function in their usual regulatory fashion. Because of patient consent and the complexities introduced by decisions that will affect an as yet nonexistent being, action must be taken to intervene in the practice of medicine where self-regulation and the usual mechanisms have failed. The rates of multiple birth pregnancies from ARTs such as IVF have already shown improvement over time. We need to decide as states and as a nation whether we are content to wait out the course of self-regulation and intervene only if the profession is unable to adequately self-correct, or whether it is better to step in early and actively advocate and legislate for better practices. Even as IVF and other ARTs are improving, drugs that induce ovarian stimulation are filling the gap left by ARTs.